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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. Trade (Proprietary) Name

ACTICOAT FLEX 7 Dressing

2. Common/Classification Name

Common Name: Silver Coated Dressing

Classification Name: Dressing

Classification Code: FRO

3. Applicant's Name & Address

Smith & Nephew, Inc.
970 Lake Carillon Drive
St. Petersburg, Florida 33716
Phone: 727-392-1261
Fax: 727-399-3468

4. Contact Information

Terry McMahon
Director, Regulatory Affairs and Compliance
Phone: 727-399-3785
Email: terry.mcmahon@smith-nephew.com

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5. Device Classification and Panel

A final classification for "dressing" has not been implemented by the General and Plastic Surgery Devices Panel. At this time, however, classification code FRO is unclassified.

6. Predicate Device

Silvelon (K981299).

The ACTICOAT FLEX 7 dressing cover by this submission is substantial equivalent to other legally marketed burn and wound dressing. The ACTICOAT FLEX 7 dressing is substantial equivalent to Argentum International LLC's Silvelon Contact Wound Dressing (K981299).

7. Other Similar Devices

ACTICOAT FLEX 7 is similar in form and function to Acticoat 7 dressings (K001519). The subject device has all features has all the features and benefits associated with a conformable dressing as well as the added benefit of an antimicrobial barrier dressing.

8. Performance Standards

No applicable performance standards have been established under Section 514 of the FD&C Act. Biocompatibility tests were done in conformance with relevant requirements of AAMI/ISO-10993. Additional standards applicable to the device include the following: ISO 13485, AAMI/ISO 11137-1, AAMI/ISO 11137-2 and ISO 15843.

9. Intended Use

ACTICOAT FLEX 7 is indicated for use on partial and full-thickness wounds for up to 7 days.

This includes:

First and second-degree burns,

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To cover grafts,

Surgical sites,

Venous ulcers,

Pressure ulcers

Diabetic ulcers.

10. Device Description

The ACTICOAT FLEX 7 dressing consists of a flexible, low adherent polyester layer coated with nanocrystalline silver.

The ACTICOAT FLEX 7 is a highly conformable dressing. nanocrystalline silver provides an effective barrier to microbial contamination The antimicrobial barrier properties of the ACTICOAT FLEX 7 dressings remain effective for up to 7 days. The antimicrobial barrier properties and the ability of the dressing to allow fluid to pass through without impairment, (*in-vitro* data) has shown ACTICOAT FLEX 7 to be compatible with negative pressure wound therapy (NPWT) for a period of up to 3 days.

The dressing is low adherent, which helps to minimise wound trauma at dressing changes.

The silver coating is derived from a silver target which 99.99% silver. The coating which is applied to the dressing is predominantly silver with a small number of oxygen atoms trapped within the coating structure. The coatings are highly porous and consist of equiaxed nanocrystals organised into coarse columnar structures. These unique physical structures, in

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combination with the oxygen atoms/molecules that are trapped in the crystal lattice, contribute to the enhanced solubility of the films.

11. Biocompatability

The biocompatibility of ACTICOAT FLEX 7 has been demonstrated through appropriate *in vivo* and *in vitro* tests including cytotoxicity, sensitization, irritation, subchronic toxicity, and genotoxicity. All tests were performed on the finished device according to the Biological Evaluation of Medical Devices Standard ISO 10993 Part 1:2003. These studies indicated that ACTICOAT FLEX 7 dressings are safe for their intended use.

In addition, the effects of the device on wound healing have been evaluated in an animal model (minipigs), and it was demonstrated that the device had no deleterious effects on wound healing.

12. Summary of Substantial Equivalence

The subject device is substantially equivalent to the predicate devices Silverlon Contact Wound and Acticoat Silver Coated Silver dressings. This subject device has similar characteristics and it provides similar functions as the predicate devices. The silver coating and process used to produce the nanocrystalline silver coating for the subject are identical to the coating and coating process used in the manufacture of Acticoat 7. The indications and instructions for use are similar.

Like the subject device the Silverlon Contact Wound product consists of an absorbent material and the dressing release silver ions into and around the wound site when activated by moisture. Both products are provided sterile to the user, and both have antimicrobial effect.

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The technological subject device and the predicate devices have similar design, materials and manufacturing methods and do not raise any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 22 2009

Smith & Nephew
% Terry McMahon
970 Lake Carillon Drive
Suite 110
St. Petersburg, Florida 33716

Re: K083113
Trade/Device Name: ACTICOAT FLEX 7 Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 14, 2009
Received: May 18, 2009

Dear Terry McMahon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known):K083113

Device Name: ACTICOAT FLEX 7 Dressing

Indications For Use:

ACTICOAT FLEX 7 is indicated for use on partial and full thickness wounds for up to 7 days.

This includes: first and second-degree burns, as a protective covering of grafts, surgical sites, venous ulcers, pressure ulcers, diabetic ulcers.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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